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10/796,863	03/09/2004	Anna Jerebko	2003P03591US01	2678

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EXAMINER	
TABATABAI, ABOLFAZL	
ART UNIT	**PAPER NUMBER**
2624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,863	JEREBKO ET AL.	
	Examiner	Art Unit	
	Abolfazl Tabatabai	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 21 is objected to because of the following informalities:

In claim 6, line 10 " claim 21 " should be corrected as " claim 20 ".

Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows:

> Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.
>
> When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and Warmerdam, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).

> In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See Lowry, 32 F.3d at 1583-84, 32 USPQ2d at 1035.

3. Claims 17-19 and 36-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows.

4. Claims 17 and 36 recite " **A program storage device readable by a machine, tangibly embodying a program of instructions executable by the machine to perform**.... " embodying functional descriptive material However, the claim does not define a computer-readable medium or memory and is thus non-statutory for that reason (i.e., "When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized" – Guidelines Annex IV). That is, the scope of the presently claimed " a computer software product " (line 1 of claim 26) can range from paper on which the program is written, to a program simply contemplated and memorized by a person. The Examiner suggests amending the claim such as "**A computer-readable medium encoded with computer executable instructions to perform** ..." or equivalent in order to make the claim statutory. Any amendment to the claim should be commensurate with its corresponding disclosure.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 2 and 4-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al (U. S. 2003/0223627 A1) in view of Heilbrun et al (U.S. 6,146,390).

Regarding claim 1, Yoshida discloses a method for automatic 3D (three-dimensional) lesion segmentation, comprising the steps of:

determining a 3D surface of a lesion in an original 3D volume space [please note, to page 5, paragraph (0081) and page 7, paragraph (0117)]; and,

extracting a volume corresponding to the lesion from the original 3D volume space using the transformed lesion surface [please note, to page 10, paragraph (0162) and page 20, paragraph (0275)].

However, Yoshida is silent about the specific details regarding the steps of:

transforming the 3D surface of the lesion to a spherical coordinate space; processing the 3D surface in the spherical coordinate space to determine a lesion surface in the spherical coordinate space which separates the lesion from surrounding normal structure; and,

transforming the lesion surface in the spherical coordinate space to the original 3D volume space.

In the same field (medical imaging) of endeavor, however, Heilbrun discloses apparatus and method for photogrametric surgical localization characterizing comprising the steps of:

transforming the 3D surface of the lesion (please note, to column 10, lines 25-35 and column 11, lines 19-26) to a spherical coordinate space (please note, to column 8, lines 50-65);

processing the 3D surface in the spherical coordinate space to determine a lesion surface in the spherical coordinate space which separates the lesion from surrounding normal structure (please note, to column 8, lines 50-65); and,

transforming the lesion surface in the spherical coordinate space to the original 3D volume space (please note, to column 10, lines 25-35 and column 11, lines 19-26). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use transforming the lesion surface in the spherical coordinate space as taught by Heilbrun in the system of Yoshida because Heilbrun provides Yoshida an improved system which is related to technique for mapping internal structures in the body of an animal or human, so this technique is reliable, and inexpensive for localizing a medical instrument relative to points of interest including both visible anatomical features and internal features imaged by volume/and or 2D methods.

Regarding claim 2, Yoshida discloses the method of claim 1, wherein the step of determining a 3D surface comprises:

extracting a 3D sub-volume from the original 3D volume space which surrounds the lesion [please note, to page 10, paragraph (0162) and page 20, paragraph (0275)]; interpolating image data in the 3D sub-volume to render the 3D sub-volume isotropic [please note, to page 20, paragraph (0275)]; and determining a 3D edge of the lesion in the isotropic 3D sub-volume [please note, to page 6, paragraph (0101) and page 9, paragraph (0146)].

Regarding claim 4, Yoshida is silent about the specific details regarding the method of claim 1, wherein the step of transforming the 3D surface of the lesion to a spherical coordinate space comprises:

determining a centroid location of the lesion in the original 3D volume space; and determining a spherical coordinate for each pixel of the 3D surface based on the centroid location; and generating a 2D representation of the 3D surface in the spherical coordinate space using the spherical coordinates.

In the same field (medical imaging) of endeavor, however, Heilbrun discloses apparatus and method for photogrametric surgical localization characterizing comprising the steps of:

determining a centroid location of the lesion in the original 3D volume space (please note, to column 12, lines 28-34); and determining a spherical coordinate for each pixel of the 3D surface based on the centroid location (please note, to column 8, lines 50-65); and generating a 2D representation of the 3D surface in the spherical coordinate space using the spherical coordinates (please note, to column 7, lines 35-41).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a centroid location of the lesion in the original 3D volume space as taught by Heilbrun in the system of Yoshida because Heilbrun provides Yoshida an improved system which is related to technique for mapping internal structures in the body of an animal or human, so this technique is reliable, and inexpensive for localizing a medical instrument relative to points of interest including both visible anatomical features and internal features imaged by volume/and or 2D methods.

Regarding claim 5, Yoshida discloses the method of claim 4, wherein the centroid location of the lesion is determined by an automated process [please note, to page 7, paragraph (0128)].

Regarding claim 6, Yoshida discloses the method of claim 4, wherein the centroid location of the lesion is selected by a user [please note, to page 5, paragraph (0081)].

Regarding claim 7, Yoshida discloses the method of claim 4, further comprising normalizing the 2D representation of the 3D surface in the spherical coordinate space [please note, to page 5, paragraph (0205)].

Regarding claim 8, Yoshida discloses the method of claim 7, further comprising median filtering the normalized 2D representation [please note, to page 8, paragraph (0134) and page 11, paragraph (0176)].

Regarding claim 9, Yoshida discloses the method of claim 4, wherein the step of processing the 3D surface in the spherical coordinate space comprises the steps of:

extending the 2D representation of the 3D surface in the spherical coordinate space [please note, to page 6, paragraph (0108)]; and interpolating the extended 2D representation to determine a separating surface that separates the lesion from an anatomical structure to which the lesion is attached [please note, to page 20, paragraph (0275)].

Regarding claim 10, Yoshida discloses the method of claim 1, wherein the step of transforming the lesion surface in the spherical coordinate space to the original 3D volume space comprises mapping vertices in the original 3D volume space to the spherical coordinate space [please note, to page 16, paragraph (0237)].

Claim 11 is similarly analyzed as claim 1 above.

Regarding claim 12, Yoshida discloses the method of claim 1, wherein the lesion is a colonic polyp [please note, to page 7, paragraph (0123)].

Regarding claim 13, Yoshida discloses the method of claim 12, wherein the step of processing the 3D surface in the spherical coordinate space to determine a lesion surface in the spherical coordinate space which separates the lesion from surrounding normal structure lesion surface, comprises the step of determining a polyp neck [please note, to page 10, paragraph (0158) and page 11, paragraph (0175)].

Regarding claim 14, Yoshida discloses the method of claim 1, further comprising the step of measuring one or more parameters associated with the extracted volume [please note, to page 19, paragraph (0270)].

Regarding claim 15, Yoshida discloses the method of claim 1; further comprising repeating the method steps in an iterative manner to obtain convergence of a volume

value [please note, to page 5, paragraph (0081)].

Regarding claim 16, Yoshida discloses the method of claim 1, further comprising the step of:

determining if the lesion surface representation in the spherical coordinate space comprises a false surface that is not actually part of the lesion [please note, to page 10, paragraph (0158) and page 17, paragraph (0251)]; and removing a false surface that is determined to be included in the lesion surface representation [please note, to page 9, paragraph (0151)].

Claim 17 is similarly analyzed as claim 1 above.

Claim 18 is similarly analyzed as claim 4 above.

Claim 19 is similarly analyzed as claim 12 above.

Claim 20 is similarly analyzed as claim 1 above.

Claim 21 is similarly analyzed as claim 2 above.

Claim 22 is similarly analyzed as claim 3 above.

Claims 23 and 24 are similarly analyzed as claim 4 above.

Regarding claim 25, Yoshida is silent about the specific details regarding the method of claim 20, further comprising the step of automatically determining the centroid location of the lesion in the first coordinate space.

In the same field (medical imaging) of endeavor, however, Heilbrun discloses apparatus and method for photogrametric surgical localization characterizing comprising the step of automatically determining the centroid location of the lesion in the first coordinate space (column 10, lines 20-23).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use automatically determining the centroid location of the lesion in the first coordinate space as taught by Heilbrun in the system of Yoshida because Heilbrun provides Yoshida an improved system which is related to technique for mapping internal structures in the body of an animal or human, so this technique is reliable, and inexpensive for localizing a medical instrument relative to points of interest including both visible anatomical features and internal features imaged by volume/and or 2D methods.

Regarding claim 26, Yoshida discloses the method of claim 20, further comprising the step of a user selecting coordinates of the centroid [please note, to page 5, paragraph (0081)].

Regarding claim 27, Yoshida discloses the method of claim 20, further comprising normalizing the transformed surface representation [please note, to page 14, paragraph (0205)].

Regarding claim 28 Yoshida discloses the method of claim 27, further comprising median filtering the normalized transformed surface representation [please note, to page 11, paragraph (0176)].

Regarding claim 29, Yoshida discloses the method of claim 20, wherein the step of processing the transformed surface representation comprises interpolating the transformed surface representation to determine a separating surface that separates the lesion from an anatomical structure to which the lesion is attached [please note, to page 20, paragraph (0275)].

Regarding claim 30, Yoshida discloses the method of claim 20, wherein the step of transforming the lesion surface in the second coordinate space back to the first coordinate space to segment the lesion from the image dataset comprises mapping vertices in the image dataset in the first coordinate space to the second coordinate space [please note, to page 16, paragraph (0237)].

Claim 31 is similarly analyzed as claim 1 above.

Regarding claim 32, Yoshida discloses the method of claim 31, further comprising the step of measuring one or more parameters associated with the segmented lesion [please note, to page 20, paragraph (0275)].

Claim 33 is similarly analyzed as claim 15 above.

Claim 34 is similarly analyzed as claim 12 above.

Claim 35 is similarly analyzed as claim 13 above.

Claim 36 is similarly analyzed as claim 1 above.

Claims 37 and 38 are similarly analyzed as claim 4 above.

Claim 39 is similarly analyzed as claim 9 above.

Claim 40 is similarly analyzed as claim 12 above.

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al (U. S. 2003/0223627 A1) and Heilbrun et al (U.S. 6,146,390) as applied to claim 1, above, and further in view of Paik et al (U. S. 7,043,064 B2).

Regarding claim 3, Yoshida is silent about the specific details regarding the method of claim 2, wherein the step of determining a 3D edge of the lesion is performed using a 3D Canny edge detection process.

In the same field (medical imaging) of endeavor, however, Paik discloses method for characterizing shapes in medical images comprises a 3D Canny edge detection process (please note, to column 5, lines 47-52).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a 3D Canny edge detection process as taught by Paik in the system of Yoshida because Paik provides Yoshida an improved system with a high detection specificity, i.e. reducing false positive, without sacrificing sensitivity of the detection of a shape of interest. Also this method is deterministic and thus, not requires any training, is very fast and easy to implement.

Other Prior Art Cited

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kenet et al (U. S. 5,836,872) disclose digital optical visualization, enhancement, quantification, and classification of surface and subsurface features of body surfaces.

Ray et al (U. S. 5,825,908) disclose anatomical visualization and measurement system.

Contact Information

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to ABOLFAZL TABATABAI whose telephone number is (571) 272-7458.

The Examiner can normally be reached on Monday through Friday from 9:30 a.m. to 7:30 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bhavesh Mehta, can be reached at (571) 272-7453. The fax

phone number for organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Abolfazl Tabatabai

Patent Examiner

Technology Division 2624

May 2, 2007

A- Tabatabai